



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

In re application of : Attorney Docket No. 2005_0747A

Yasuo HAYASHI et al. : **Confirmation No. 4714**

Serial No. 10/534,423 : Group Art Unit 1619

Filed May 10, 2005 : Examiner Christopher R. Lea

METHOD FOR PRODUCING ORALLY
ADMINISTRABLE EDIBLE AGENT OF
LAMINATE FILM FORM AND PRESSURE
BONDING APPARATUS OF THE AGENT :

Mail Stop: Appeal Brief-Patents

APPEAL BRIEF

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

The following is Appellants' Brief, submitted under the provisions of 37 CFR 41.37.
Pursuant to the provisions of 37 CFR 41.200, this Brief is submitted with a fee of \$270.00.

01/20/2010 SMOHAMME 000000068 10534423

01 FC:2402

270.00 0P

REAL PARTY IN INTEREST

The real party in interest is Kyukyu Pharmaceutical Co., Ltd. of Tokyo, Japan, the assignee of the present invention.

RELATED APPEALS AND INTERFERENCES

There are no known related appeals or interferences.

STATUS OF CLAIMS

Claims 1-38 have been cancelled. Claims 39-76 stand finally rejected.

The Appellants now appeal the rejection of claims 39-76.

STATUS OF AMENDMENTS

No amendments subsequent to the final rejection of July 16, 2009 have been made.

SUMMARY OF THE CLAIMED SUBJECT MATTER

A description of the subject matter of each of the independent claims involved in the appeal is presented below with reference to the written description and drawings of this application. It is noted that the following description is made with reference to the specification as originally filed.

Independent Claim 39

The subject matter of independent claim 39 is directed to a method for producing an orally administrable edible agent of laminate film form. The method includes forming a plurality of orally administrable edible agent layers 210, wherein each orally administrable edible agent layer 210 has a predetermined thickness and is formed on a surface of a respective resin film 202 (in Fig. 1), 12a and 12b (in Fig. 2) by coating and drying (see page 36, line 14 through page 37, line 6; page 38, lines 1-27; and Figs. 1-2). The method also includes joining together two orally administrable edible agent layers so that orally administrable edible agent layer surfaces face each other and the orally administrable edible agent layers are sandwiched between the resin films 12a, 12b of the two orally administrable edible agent layers, and pressurizing the resin

films 12a, 12b at back surfaces by a pair of press rolls 11 so as to bond the orally administrable edible agent layers together such that ingredients of each of the orally administrable edible agent layers do not permeate the other of the orally administrable edible agent layers (see page 38, lines 14-28; page 41, lines 1-13; page 77, lines 16-23; and Fig. 2), wherein the orally administrable edible agent layers include the same ingredients or different ingredients (see page 11, lines 9-13).

The method of claim 39 also includes delaminating only one of the two resin films by conveying the two resin films 12a, 12b sandwiching the bonded orally administrable edible agent layers in a substantially tangential direction at a pressurization zone of the pair of press rolls 11, and drawing only one (12a) of the two resin films 12a, 12b sandwiching the bonded orally administrable edible agent layers in a direction different from the conveying direction along a peripheral surface of a delamination roll 13 disposed in the conveying direction while continuously conveying the other resin film (12b) retaining the bonded orally administrable edible agent layers in the conveying direction (see page 42, lines 6-15; and Fig. 2).

Independent Claim 49

The subject matter of independent claim 49 is directed to a method for producing an orally administrable edible agent of laminate film form. The method includes forming a plurality of orally administrable edible agent layers 210, wherein each orally administrable edible agent layer 210 has a predetermined thickness and is formed on a surface of a respective resin film 202 (in Fig. 1), 12a and 12b (in Fig. 2) by coating and drying (see page 36, line 14 through page 37, line 6; page 38, lines 1-27; and Figs. 1-2). The method also includes joining together first and second orally administrable edible agent layers so that orally administrable edible agent layer surfaces face each other and the orally administrable edible agent layers are sandwiched between corresponding first and second resin films 12a, 12b of the first and second orally administrable edible agent layers, and pressurizing the resin films 12a, 12b at back surfaces by a pair of press rolls 11 so as to bond the orally administrable edible agent layers together such that ingredients of each of the first and second orally administrable edible agent layers do not permeate the other of the first and second orally administrable edible agent layers (see page 38, lines 14-28; page 41, lines 1-13; page 77, lines 16-23; and Fig. 2), wherein the orally administrable edible agent layers include the same ingredients or different ingredients (see page 11, lines 9-13).

The method of claim 49 also includes delaminating only one of the first and second resin films 12a, 12b by conveying the first and second resin films 12a, 12b sandwiching the bonded orally administrable edible agent layers in a substantially tangential direction at a pressurization zone of the pair of press rolls 11, and drawing only one (12a) of the first and second resin films 12a, 12b sandwiching the bonded orally administrable edible agent layers in a direction different from the conveying direction along a peripheral surface of a delamination roll 13 disposed in the conveying direction while continuously conveying the other (12b) of the first and second resin films retaining the bonded orally administrable edible agent layers in the conveying direction (see page 42, lines 6-15; and Fig. 2).

Further, the method of claim 49 includes joining together a third orally administrable edible agent layer and the bonded first and second orally administrable edible agent layers so that orally administrable edible agent layer surfaces face each other and the first, second and third orally administrable edible agent layers are sandwiched between a corresponding third resin film of the third orally administrable edible agent layer and the other of the first and second resin films retaining the bonded first and second orally administrable edible agent layers, and pressurizing the resin films at back surfaces by the pair of press rolls 11 so as to bond the first, second and third orally administrable edible agent layers together (see page 43, line 6 through page 44, line 6; page 71, line 11 through page 74, line 15; and Figs. 2 and 17(A)-(D)) such that ingredients of each of the orally administrable edible agent layers do not permeate any other of the orally administrable edible agent layers (see page 77, lines 16-23), wherein the third orally administrable edible agent layer includes the same ingredients or different ingredients as that of the bonded first and second orally administrable edible agent layers (see page 27, lines 7-20).

The method of claim 49 further includes delaminating only one of the resin films sandwiching the bonded first, second and third orally administrable edible agent layers by conveying the resin films sandwiching the bonded first, second and third orally administrable edible agent layers in the substantially tangential direction at the pressurization zone of the pair of press rolls 11, and drawing only one of the resin films sandwiching the bonded first, second and third orally administrable edible agent layers in a direction different from the conveying direction along the peripheral surface of the delamination roll 13 disposed in the conveying direction while continuously conveying the other of the resin films retaining the first, second and third orally administrable edible agent layers in the conveying direction (see page 42, lines 6-15;

page 43, line 6 through page 44, line 6; page 71, line 11 through page 74, line 15; and Figs. 2 and 17(A)-(D)).

Independent Claim 56

The subject matter of independent claim 56 is directed to a method for producing an orally administrable edible agent of laminate film form. The method includes forming a plurality of orally administrable edible agent layers 210, wherein each orally administrable edible agent layer 210 has a predetermined thickness and is formed on a surface of a respective resin film 202 (in Fig. 1), 12a and 12b (in Fig. 2) by coating and drying (see page 36, line 14 through page 37, line 6; page 38, lines 1-27; and Figs. 1-2), and winding each of the orally administrable edible agent layers into a roll so as to form a plurality of rolled films 17, 19 (see page 38, lines 5-8; page 41, lines 3-8; and Figs. 1-2).

The method of claim 56 also includes unwinding and joining together two rolled films 17, 19 so that surfaces of the orally administrable edible agent layers of the two rolled films 17, 19 face each other and the orally administrable edible agent layers are sandwiched between the resin films 12a, 12b of the two rolled films 17, 19, and pressurizing the resin films 12a, 12b at back surfaces by a pair of press rolls 11 so as to bond the orally administrable edible agent layers together such that ingredients of each of the orally administrable edible agent layers do not permeate the other of the orally administrable edible agent layers (see page 38, lines 14-28; page 41, lines 1-13; page 77, lines 16-23; and Fig. 2), wherein the orally administrable edible agent layers include the same ingredients or different ingredients (see page 11, lines 9-13).

Further, the method of claim 56 includes delaminating only one of the two resin films 12a, 12b by conveying the two resin films 12a, 12b sandwiching the bonded orally administrable edible agent layers in a substantially tangential direction at a pressurization zone of the pair of press rolls 11, and drawing only one (12a) of the two resin films 12a, 12b sandwiching the bonded orally administrable edible agent layers in a direction different from the conveying direction along a peripheral surface of a delamination roll 13 disposed in the conveying direction while continuously conveying the other resin film (12b) retaining the bonded orally administrable edible agent layers in the conveying direction (see page 42, lines 6-15; and Fig. 2).

Independent Claim 62

The subject matter of independent claim 62 is directed to a method for producing an orally administrable edible agent of laminate film form. The method includes forming a plurality of orally administrable edible agent layers 210, wherein each orally administrable edible agent layer 210 has a predetermined thickness and is formed on a surface of a respective resin film 202 (in Fig. 1), 12a and 12b (in Fig. 2) by coating and drying (see page 36, line 14 through page 37, line 6; page 38, lines 1-27; and Figs. 1-2), and winding each of the orally administrable edible agent layers into a roll so as to form a plurality of rolled films 17, 19 (see page 38, lines 5-8; page 41, lines 3-8; and Figs. 1-2).

The method of claim 62 also includes unwinding and joining together first and second rolled films 17, 19 so that surfaces of corresponding first and second orally administrable edible agent layers of the first and second rolled films 17, 19 face each other and the orally administrable edible agent layers are sandwiched between corresponding first and second resin films 12a, 12b of the first and second rolled films 17, 19, and pressurizing the resin films 12a, 12b at back surfaces by a pair of press rolls 11 so as to bond the orally administrable edible agent layers together such that ingredients of each of the first and second orally administrable edible agent layers do not permeate the other of the first and second orally administrable edible agent layers (see page 38, lines 14-28; page 41, lines 1-13; page 77, lines 16-23; and Fig. 2, wherein the orally administrable edible agent layers include the same ingredients or different ingredients (see page 11, lines 9-13).

Further, the method of claim 62 includes delaminating only one of the first and second resin films 12a, 12b by conveying the first and second resin films 12a, 12b sandwiching the bonded orally administrable edible agent layers in a substantially tangential direction at a pressurization zone of the pair of press rolls 11, and drawing only one (12a) of the first and second resin films 12a, 12b sandwiching the bonded orally administrable edible agent layers in a direction different from the conveying direction along a peripheral surface of a delamination roll 13 disposed in the conveying direction while continuously conveying the other (12b) of the first and second resin films 12a, 12b retaining the bonded first and second orally administrable edible agent layers in the conveying direction (see page 42, lines 6-15; and Fig. 2). The method of claim 62 also includes winding the resin film retaining the bonded orally administrable edible agent layers into a roll 12c (see page 43, lines 6-12).

In addition, the method of claim 62 includes unwinding and joining together a third rolled film and the roll 12c having the bonded first and second orally administrable edible agent layers so that surfaces of a corresponding third orally administrable edible agent layer of the third rolled film and one of the first and second orally administrable edible agent layers face each other and the first, second and third orally administrable edible agent layers are sandwiched between a corresponding third resin film of the third rolled film and the other of the first and second resin films retaining the bonded first and second orally administrable edible agent layers, and pressurizing the resin films at back surfaces by the pair of press rolls 11 so as to bond the first, second and third orally administrable edible agent layers together (see page 43, line 6 through page 44, line 6; page 71, line 11 through page 74, line 15; and Figs. 2 and 17(A)-(D)) such that ingredients of each of the orally administrable edible agent layers do not permeate any other of the orally administrable edible agent layers (see page 77, lines 16-23), wherein the third orally administrable edible agent layer includes the same ingredients or different ingredients as that of the bonded first and second orally administrable edible agent layers (see page 27, lines 7-20).

Further, the method of claim 62 includes delaminating only one of the resin films sandwiching the bonded first, second and third orally administrable edible agent layers by conveying the resin films sandwiching the bonded first, second and third orally administrable edible agent layers in the substantially tangential direction at the pressurization zone of the pair of press rolls 11, and drawing only one of the resin films sandwiching the bonded first, second and third orally administrable edible agent layers in a direction different from the conveying direction along the peripheral surface of the delamination roll 13 disposed in the conveying direction while continuously conveying the other of the resin films retaining the bonded first, second and third orally administrable edible agent layers in the conveying direction (see page 42, lines 6-15; page 43, line 6 through page 44, line 6; page 71, line 11 through page 74, line 15; and Figs. 2 and 17(A)-(D)).

Independent Claim 69

The subject matter of independent claim 69 is directed to a pressure bonding apparatus for producing an orally administrable edible agent of laminate film form, comprising a pair of press rolls 11 arranged to draw two resin films 12a, 12b, each of the resin films 12a, 12b being provided with an orally administrable edible agent layer having a predetermined thickness on a

surface thereof, such that orally administrable edible agent layer surfaces face each other and the orally administrable edible agent layers are sandwiched between the resin films 12a, 12b, with the pair of press rolls 11 being further arranged to pressurize the resin films 12a, 12b at back surfaces thereof so as to bond the orally administrable edible agent layers together such that ingredients of each of the orally administrable edible agent layers do not permeate the other of the orally administrable edible agent layers (see page 38, lines 14-28; page 77, lines 16-23; and Fig. 2).

The pressure bonding apparatus of claim 69 also includes a delamination roll 13 having a diameter of 6 cm or less disposed at a position forward of the pair of press rolls 11 in a conveying direction of the pair of press rolls 11 and in a substantially tangential direction at a pressurization zone of the pair of press rolls 11 (see page 39, line 20 through page 40, line 15; and Figs. 2-4), and a winding shaft 14 arranged to draw and delaminate only one (12a) of the two resin films 12a, 12b sandwiching the orally administrable edible agent layers conveyed from the pair of press rolls 11 to the delamination roll 13 in a direction different from the conveying direction from the pair of press rolls 11 to the delamination roll 13, along a peripheral surface of the delamination roll 13 (see page 39, line 28 through page 40, line 7; and Figs. 2 and 4). Further, the pressure bonding apparatus of claim 69 includes a conveyance mechanism arranged to convey the other (12b) of the two resin films 12a, 12b, which retains the orally administrable edible agent layers, in the conveying direction from the pair of press rolls 11 to the delamination roll 13 (see page 39, lines 1-8; and Fig. 2).

GROUND OF REJECTION TO BE REVIEWED ON APPEAL

Claims 39-76 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Roreger et al. (WO 02/51815, using U.S. 6,818,087 as an English translation) in view of Nogami (WO 02/87622, using U.S. 2004/0137040 as an English translation).

ARGUMENT

I. Rejection under 35 U.S.C. § 103(a) over Roreger et al. (WO 02/51815, using U.S. 6,818,087 as an English translation) (hereinafter “Roreger”) in view of Nogami (WO 02/87622, using U.S. 2004/0137040 as an English translation) (hereinafter “Nogami”).

Claims 39-48 and 56-61

Independent claims 39 and 56 each recite a method for producing an orally administrable edible agent of laminate film form. The methods of claims 39 and 56 include: (1) forming a plurality of orally administrable edible agent layers, wherein *each orally administrable edible agent layer is formed on a surface of a respective resin film* by coating and drying; (2) joining together two orally administrable edible agent layers so that orally administrable edible agent layer surfaces face each other and the orally administrable edible agent layers are sandwiched between corresponding resin films of the two orally administrable edible agent layers; and (3) *delaminating only one of the two resin films by conveying the two resin films sandwiching the bonded orally administrable edible agent layers in a substantially tangential direction at a pressurization zone of the pair of press rolls.*

Roreger discloses a method in which an active ingredient is applied to a base layer 1 by an applicator nozzle 12, and that a base layer 2 is laminated on the base layer 1 so as to seal the active ingredient within the base layers 1, 2 for maturation (see Roreger at column 3, lines 28-45; and Fig. 1). Further, Roreger discloses that each base layer 1, 2 includes protective layers 3, 4 which may be detachable (see Roreger at column 4, lines 39-41).

Initially, it is noted that independent claims 39 and 56 recite forming a plurality of orally administrable edible agent layers, wherein each orally administrable edible agent layer is formed on a surface of a respective resin film. In this regard, it is noted that Roreger discloses that the active substance is applied to a surface of at least one of the base layers 1 and 2 (see Roreger at column 3, lines 36-37). Thus, in the response filed on May 5, 2009, it was noted that the base layers 1 and 2 of Roreger correspond to the resin films of the claimed invention (*i.e.*, the films on which the edible agent layers are formed) (see response filed on May 5, 2009 at page 16, lines 21-29). Accordingly, Roreger does not disclose or suggest delaminating only one of the two “resin films” as required by independent claims 39 and 56, because Roreger discloses that the base layers 1 and 2 are irreversibly bonded, and that it is necessary that the interfaces of the base layers 1 and 2 are bonded inseparably (see Roreger at column 5, line 66 through column 6, line 5).

However, during the telephone interview of October 8, 2009, the Examiner clarified that the layers 1 and 2 are being interpreted as also including the active ingredient, and are thus being

interpreted as the “edible agent layers” of independent claims 39 and 56, and that the protective layers 3, 4 are being interpreted as the “resin films” of independent claims 39 and 56.

In this regard, it is first noted that Roreger clearly discloses that reference numbers 1 and 2 correspond to layers of the matrix base material, that the active substance is applied to at least one of the layers 1, 2, and that both base material layers 1, 2 (and not the active ingredients) are joined together such that the active substance medium does not emerge at the edges of the weblike matrix 14 and such that the interfaces of the base material layers 1, 2 are bonded inseparably, as shown in Fig. 2 (see Roreger at column 3, lines 36-37; column 4, lines 38-39; column 5, line 66 through column 6, line 5; and Fig. 2). Thus, as Roreger clearly discloses that the reference numbers 1 and 2 correspond to the base material layers, and that the active substance is formed on the layers 1 and 2 as shown in Fig. 2, it is respectfully submitted that the layers 1 and 2 do not constitute the edible agent layers of claims 39 and 56.

Rather, it is respectfully submitted that the layers 1 and 2 correspond to the resin films of the claimed invention (*i.e.*, the films on which the edible agent layers are formed). As indicated above, Roreger does not disclose or suggest delaminating only one of the two “resin films” as required by independent claims 39 and 56, because Roreger discloses that the base layers 1 and 2 are irreversibly bonded, and that it is necessary that the interfaces of the base layers 1 and 2 are bonded inseparably (see Roreger at column 5, line 66 through column 6, line 5).

Further, even if the interpretation of the base material layers 1 and 2 as the edible agent layers is proper and the interpretation of the protective layers 3 and 4 as the resin layers of independent claims 39 and 56 is proper, Roreger does not disclose *delaminating only one of the two resin films by conveying the two resin films sandwiching the bonded orally administrable edible agent layers* in a substantially tangential direction at a pressurization zone of the pair of press rolls, as required by independent claims 39 and 56.

Rather, Roreger discloses that protective layers 3 and 4 are removed from the base layers 1 and 2 prior to application of the active substance (see Roreger at column 4, lines 46-49). Thus, Roreger does not disclose delaminating only one of the two resin films by conveying the two resin films sandwiching the bonded orally administrable edible agent layers, as required by independent claims 39 and 56, because Roreger discloses that the protective layers 3 and 4 are removed prior to the application of the active substance, and therefore the protective layers 3 and 4 never sandwich the active substance.

Further, as noted by the Examiner on page 6 of the Office Action of July 16, 2009, Roreger does not disclose an orally administrable edible agent of laminate film form (see Office Action of July 16, 2009 at page 6, lines 9-11). In this regard, the Examiner cites Nogami as disclosing a layered edible film for administering an active agent in which the layers are sprayed onto a film and dried, and concludes that it would have been obvious to one of ordinary skill in the art to make the layered edible film of Nogami by the method of Roreger so as to arrive at the claimed invention (see Office Action of July 16, 2009 at page 6, lines 12-15; and page 7, line 20 through page 8, line 1).

Nogami discloses an orally administered agent which includes a combination of drug-containing layers 11, water-swellaable gel-forming layers 12, and intermediate layers 13 (see Nogami at paragraph [0082], lines 1-5; and Fig. 5). In the response filed on May 5, 2009, it was argued that Nogami, like Roreger, does not disclose or suggest delaminating only one of the two resin films by conveying the two resin films sandwiching the bonded orally administrable edible agent layers in a substantially tangential direction at a pressurization zone of the pair of press rolls, and drawing only one of the two resin films sandwiching the bonded orally administrable edible agent layers in a direction different from the conveying direction along a peripheral surface of a delamination roll disposed in the conveying direction while continuously conveying the other resin film retaining the bonded orally administrable edible agent layers in the conveying direction, as required by independent claims 39 and 56 (see response filed on May 5, 2009 at page 19, lines 14-22). In response to this argument, however, the Examiner cites paragraph [0113] of Nogami as disclosing the removal of a support film from the orally administered agent, and notes that the determination of when to remove the support film and which films to remove are certainly within the purview of the skilled artisan (see Office Action of July 16, 2009 at page 9, lines 1-5).

However, with regard to Appellants' assertion that the base layers 1 and 2 of Roreger correspond to the resin layers of the claimed invention, it is noted that MPEP § 2143.01(V) states that a "proposed modification cannot render the prior art unsatisfactory for its intended purposed." As indicated above, Roreger discloses an active ingredient layer formed on base layers 1 and 2, and that the base layers 1 and 2 are irreversibly bonded, and that it is necessary that the interfaces of the base layers 1 and 2 are bonded inseparably (see Roreger at column 5, line 66 through column 6, line 5). Thus, it is respectfully submitted that modifying the Roreger

reference by removing one of the films on which the orally administrable edible agent layer is formed (*i.e.*, base layers 1 and 2) would render Roreger unsatisfactory for its intended purpose, as Roreger explicitly discloses that the base layers 1 and 2 are irreversibly bonded, and that it is necessary that the interfaces of the base layers 1 and 2 are bonded inseparably. Accordingly, one of ordinary skill in the art would not have modified the Roreger reference by removing one of the base layers 1 and 2, as Roreger explicitly teaches away from such a modification.

With regard to the Examiner's interpretation of the protective layers 3 and 4 as the resin layers of independent claims 39 and 56, it is first noted that paragraph [0113] of Nogami merely discloses that the administered agent is "peeled off" of the support film (see Nogami at paragraph [0113], page 10, lines 2-5), and does not disclose or even remotely suggest delaminating only one of the two resin films by conveying the two resin films sandwiching the bonded orally administrable edible agent layers in a substantially tangential direction at a pressurization zone of the pair of press rolls, as required by independent claims 39 and 56.

With further regard to the Examiner's interpretation of the protective layers 3 and 4 as the resin layers of independent claims 39 and 56, it is noted that Roreger only discloses that protective layers 3 and 4 are removed from the base layers 1 and 2 prior to application of the active substance, and prior to the laminating unit 13 (see Roreger at column 4, lines 46-49; and Fig. 1). As such, the protective layers 3 and 4 never sandwich the active substance since Roreger discloses that the protective layers 3 and 4 are removed prior to the application of the active substance (see Roreger at column 4, lines 46-49), and therefore does not disclose a method which includes delaminating only one of the two resin films by conveying the two resin films sandwiching the bonded orally administrable edible agent layers in a substantially tangential direction at a pressurization zone of the pair of press rolls, as required by independent claims 39, and 56.

Accordingly, as none of the Roreger and Nogami references discloses or suggests delaminating only one of the two resin films by conveying the two resin films sandwiching the bonded orally administrable edible agent layers in a substantially tangential direction at a pressurization zone of the pair of press rolls, as required by independent claims 39 and 56, the combination of the Roreger and Nogami references does not disclose or suggest delaminating only one of the two resin films by conveying the two resin films sandwiching the bonded orally administrable edible agent layers in a substantially tangential direction at a pressurization zone of

the pair of press rolls, as required by independent claims 39 and 56. Accordingly, it is respectfully submitted that one of ordinary skill in the art would not have modified Roreger in view of Nogami so as to result in or render obvious the invention of independent claims 39 and 56.

Therefore, in view of the above, it is respectfully submitted that independent claims 39 and 56 are clearly allowable over the prior art of record. Further, it is respectfully submitted that claims 40-48 and 57-61 are also allowable over the prior art, at least by virtue of their dependency from claims 39 and 56, respectively.

Claims 49-55 and 62-68

Independent claims 49 and 62 each recite a method for producing an orally administrable edible agent of laminate film form. The methods of claims 49 and 62 include: (1) forming a plurality of orally administrable edible agent layers, wherein *each orally administrable edible agent layer is formed on a surface of a respective resin film* by coating and drying; (2) joining together first and second orally administrable edible agent layers so that orally administrable edible agent layer surfaces face each other and the orally administrable edible agent layers are sandwiched between corresponding resin films of the two orally administrable edible agent layers; (3) *delaminating only one of the first and second resin films by conveying the first and second resin films sandwiching the bonded orally administrable edible agent layers in a substantially tangential direction at a pressurization zone of the pair of press rolls*; (4) joining together a third orally administrable edible agent layer and the bonded first and second orally administrable edible agent layers so that the first, second and third orally administrable edible agent layers are sandwiched between a corresponding third resin film of the third orally administrable edible agent layer and the other of the first and second resin films retaining the bonded first and second orally administrable edible agent layers; and (5) delaminating only one of the resin films sandwiching the bonded first, second and third orally administrable edible agent layers by conveying the resin films sandwiching the bonded first, second and third orally administrable edible agent layers in the substantially tangential direction at the pressurization zone of the pair of press rolls.

Roreger discloses a method in which an active ingredient is applied to a base layer 1 by an applicator nozzle 12, and that a base layer 2 is laminated on the base layer 1 so as to seal the

active ingredient within the base layers 1, 2 for maturation (see Roreger at column 3, lines 28-45; and Fig. 1). Further, Roreger discloses that each base layer 1, 2 includes protective layers 3, 4 which may be detachable (see Roreger at column 4, lines 39-41).

Initially, it is noted that independent claims 49 and 62 recite forming a plurality of orally administrable edible agent layers, wherein each orally administrable edible agent layer is formed on a surface of a respective resin film. As indicated above with respect to claims 39 and 56, it is noted that Roreger discloses that the active substance is applied to a surface of at least one of the base layers 1 and 2 (see Roreger at column 3, lines 36-37), and therefore that the base layers 1 and 2 of Roreger correspond to the resin films of the claimed invention (*i.e.*, the films on which the edible agent layers are formed). Accordingly, Roreger does not disclose or suggest delaminating only one of the first and second “resin films” as required by independent claims 49 and 62, because Roreger discloses that the base layers 1 and 2 are irreversibly bonded, and that it is necessary that the interfaces of the base layers 1 and 2 are bonded inseparably (see Roreger at column 5, line 66 through column 6, line 5).

However, during the telephone interview of October 8, 2009, the Examiner clarified that the layers 1 and 2 are being interpreted as also including the active ingredient, and are thus being interpreted as the “edible agent layers” of independent claims 49 and 62, and that the protective layers 3, 4 are being interpreted as the “resin films” of independent claims 49 and 62.

In this regard, it is first noted that Roreger clearly discloses that reference numbers 1 and 2 correspond to layers of the matrix base material, that the active substance is applied to at least one of the layers 1, 2, and that both base material layers 1, 2 (and not the active ingredients) are joined together such that the active substance medium does not emerge at the edges of the weblike matrix 14 and such that the interfaces of the base material layers 1, 2 are bonded inseparably, as shown in Fig. 2 (see Roreger at column 3, lines 36-37; column 4, lines 38-39; column 5, line 66 through column 6, line 5; and Fig. 2). Thus, as Roreger clearly discloses that the reference numbers 1 and 2 correspond to the base material layers, and that the active substance is formed on the layers 1 and 2 as shown in Fig. 2, it is respectfully submitted that the layers 1 and 2 do not constitute the edible agent layers of claims 49 and 62.

Rather, it is respectfully submitted that the layers 1 and 2 correspond to the resin films of the claimed invention (*i.e.*, the films on which the edible agent layers are formed). As indicated above, Roreger does not disclose or suggest delaminating only one of the first and second “resin

films” as required by independent claims 49 and 62, because Roreger discloses that the base layers 1 and 2 are irreversibly bonded, and that it is necessary that the interfaces of the base layers 1 and 2 are bonded inseparably (see Roreger at column 5, line 66 through column 6, line 5).

Further, even if the interpretation of the base material layers 1 and 2 as the edible agent layers is proper and the interpretation of the protective layers 3 and 4 as the resin layers of independent claims 49 and 62 is proper, Roreger does not disclose *delaminating only one of the first and second resin films by conveying the first and second resin films sandwiching the bonded orally administrable edible agent layers* in a substantially tangential direction at a pressurization zone of the pair of press rolls, as required by independent claims 49 and 62.

Rather, Roreger discloses that protective layers 3 and 4 are removed from the base layers 1 and 2 prior to application of the active substance (see Roreger at column 4, lines 46-49). Thus, Roreger does not disclose delaminating only one of the first and second resin films by conveying the first and second resin films sandwiching the bonded orally administrable edible agent layers, as required by independent claims 49 and 62, because Roreger discloses that the protective layers 3 and 4 are removed prior to the application of the active substance, and therefore the protective layers 3 and 4 never sandwich the active substance.

In addition, as Roreger does not disclose delaminating only one of the first and second resin films by conveying the first and second resin films sandwiching the bonded orally administrable edible agent layers in a substantially tangential direction at a pressurization zone of the pair of press rolls, for the reasons discussed above, as required by independent claims 49 and 62, it is respectfully submitted the Roreger also does not disclose *joining together a third orally administrable edible agent layer and the bonded first and second orally administrable edible agent layers so that the first, second and third orally administrable edible agent layers are sandwiched between a corresponding third resin film of the third orally administrable edible agent layer and the other of the first and second resin films and delaminating only one of the resin films sandwiching the bonded first, second and third orally administrable edible agent layers by conveying the resin films sandwiching the bonded first, second and third orally administrable edible agent layers in the substantially tangential direction at the pressurization zone of the pair of press rolls*, as required by independent claims 49 and 62.

Further, as noted by the Examiner on page 6 of the Office Action of July 16, 2009, Roreger does not disclose an orally administrable edible agent of laminate film form (see Office Action of July 16, 2009 at page 6, lines 9-11). In this regard, the Examiner cites Nogami as disclosing a layered edible film for administering an active agent in which the layers are sprayed onto a film and dried, and concludes that it would have been obvious to one of ordinary skill in the art to make the layered edible film of Nogami by the method of Roreger so as to arrive at the claimed invention (see Office Action of July 16, 2009 at page 6, lines 12-15; and page 7, line 20 through page 8, line 1).

Nogami discloses an orally administered agent which includes a combination of drug-containing layers 11, water-swelling gel-forming layers 12, and intermediate layers 13 (see Nogami at paragraph [0082], lines 1-5; and Fig. 5). However, Nogami, like Roreger, does not disclose or suggest delaminating only one of the first and second resin films by conveying the first and second resin films sandwiching the bonded orally administrable edible agent layers in a substantially tangential direction at a pressurization zone of the pair of press rolls, joining together a third orally administrable edible agent layer and the bonded first and second orally administrable edible agent layers, and delaminating only one of the resin films sandwiching the bonded first, second and third orally administrable edible agent layers by conveying the resin films sandwiching the bonded first, second and third orally administrable edible agent layers in the substantially tangential direction at the pressurization zone of the pair of press rolls, as required by independent claims 49 and 62. In this regard, however, the Examiner cites paragraph [0113] of Nogami as disclosing the removal of a support film from the orally administered agent, and notes that the determination of when to remove the support film and which films to remove are certainly within the purview of the skilled artisan (see Office Action of July 16, 2009 at page 9, lines 1-5).

However, with regard to Appellants' assertion that the base layers 1 and 2 of Roreger correspond to the resin layers of the claimed invention, it is noted that MPEP § 2143.01(V) states that a "proposed modification cannot render the prior art unsatisfactory for its intended purposed." As indicated above, Roreger discloses an active ingredient layer formed on base layers 1 and 2, and that the base layers 1 and 2 are irreversibly bonded, and that it is necessary that the interfaces of the base layers 1 and 2 are bonded inseparably (see Roreger at column 5, line 66 through column 6, line 5). Thus, it is respectfully submitted that modifying the Roreger

reference by removing one of the films on which the orally administrable edible agent layer is formed (*i.e.*, base layers 1 and 2) would render Roreger unsatisfactory for its intended purpose, as Roreger explicitly discloses that the base layers 1 and 2 are irreversibly bonded, and that it is necessary that the interfaces of the base layers 1 and 2 are bonded inseparably. Accordingly, one of ordinary skill in the art would not have modified the Roreger reference by removing one of the base layers 1 and 2, as Roreger explicitly teaches away from such a modification.

With regard to the Examiner's interpretation of the protective layers 3 and 4 as the resin layers of independent claims 49 and 62, it is first noted that paragraph [0113] of Nogami merely discloses that the administered agent is "peeled off" of the support film (see Nogami at paragraph [0113], page 10, lines 2-5), and does not disclose or even remotely suggest delaminating only one of the first and second resin films by conveying the first and second resin films sandwiching the bonded orally administrable edible agent layers in a substantially tangential direction at a pressurization zone of the pair of press rolls, as required by independent claims 49 and 62. In addition, Nogami also does not disclose or suggest joining together a third orally administrable edible agent layer and the bonded first and second orally administrable edible agent layers and delaminating only one of the resin films sandwiching the bonded first, second and third orally administrable edible agent layers by conveying the resin films sandwiching the bonded first, second and third orally administrable edible agent layers in the substantially tangential direction at the pressurization zone of the pair of press rolls, as required by independent claims 49 and 62.

With further regard to the Examiner's interpretation of the protective layers 3 and 4 as the resin layers of independent claims 49 and 62, it is noted that Roreger only discloses that protective layers 3 and 4 are removed from the base layers 1 and 2 prior to application of the active substance, and prior to the laminating unit 13 (see Roreger at column 4, lines 46-49; and Fig. 1). As such, the protective layers 3 and 4 never sandwich the active substance since Roreger discloses that the protective layers 3 and 4 are removed prior to the application of the active substance (see Roreger at column 4, lines 46-49), and therefore does not disclose a method which includes delaminating only one of the first and second resin films by conveying the first and second resin films sandwiching the bonded orally administrable edible agent layers in a substantially tangential direction at a pressurization zone of the pair of press rolls, as required by independent claims 49 and 62.

Further, as the protective layers 3 and 4 of Roreger never sandwich the active substance since Roreger discloses that the protective layers 3 and 4 are removed prior to the application of the active substance (see Roreger at column 4, lines 46-49), Roreger also does not disclose a method which includes joining together a third orally administrable edible agent layer and the bonded first and second orally administrable edible agent layers and delaminating only one of the resin films sandwiching the bonded first, second and third orally administrable edible agent layers by conveying the resin films sandwiching the bonded first, second and third orally administrable edible agent layers in the substantially tangential direction at the pressurization zone of the pair of press rolls, as required by independent claims 49 and 62.

Accordingly, as none of the Roreger and Nogami references discloses or suggests a method which includes (i) delaminating only one of the first and second resin films by conveying the first and second resin films sandwiching the bonded orally administrable edible agent layers in a substantially tangential direction at a pressurization zone of the pair of press rolls, (ii) joining together a third orally administrable edible agent layer and the bonded first and second orally administrable edible agent layers and (iii) delaminating only one of the resin films sandwiching the bonded first, second and third orally administrable edible agent layers by conveying the resin films sandwiching the bonded first, second and third orally administrable edible agent layers in the substantially tangential direction at the pressurization zone of the pair of press rolls, as required by independent claims 49 and 62, the combination of the Roreger and Nogami references does not disclose or suggest features (i)-(iii) identified above, as required by independent claims 49 and 62. Accordingly, it is respectfully submitted that one of ordinary skill in the art would not have modified Roreger in view of Nogami so as to result in or render obvious the invention of independent claims 49 and 62.

Therefore, in view of the above, it is respectfully submitted that independent claims 49 and 62 are clearly allowable over the prior art of record. Further, it is respectfully submitted that claims 50-55 and 63-68 are also allowable over the prior art, at least by virtue of their dependency from claims 49 and 62, respectively.

Claims 69-76

Independent claim 69 recites a pressure bonding apparatus for producing an orally administrable edible agent of laminate film form, which includes a pair of press rolls arranged to

draw two resin films, with each of the resin films being provided with an orally administrable edible agent layer having a predetermined thickness on a surface thereof, such that orally administrable edible agent layer surfaces face each other and the orally administrable edible agent layers are sandwiched between the resin films, and with the pair of press rolls being further arranged to pressurize the resin films at back surfaces thereof so as to bond the orally administrable edible agent layers together such that ingredients of each of said orally administrable edible agent layers do not permeate the other of said orally administrable edible agent layers. The pressure bonding apparatus of claim 69 also includes a delamination roll having a diameter of 6 cm or less disposed at a position forward of the pair of press rolls in a conveying direction of the pair of press rolls and in a substantially tangential direction at a pressurization zone of the pair of press rolls.

Further, claim 69 recites *a winding shaft arranged to draw and delaminate only one of the two resin films sandwiching the orally administrable edible agent layers conveyed from the pair of press rolls to the delamination roll in a direction different from the conveying direction from the pair of press rolls to the delamination roll, along a peripheral surface of the delamination roll, and a conveyance mechanism arranged to convey the other of the two resin films, which retains the orally administrable edible agent layers, in the conveying direction from the pair of press rolls to the delamination roll.*

Roreger discloses a method in which an active ingredient is applied to a base layer 1 by an applicator nozzle 12, and that a base layer 2 is laminated on the base layer 1 at rollers 13 so as to seal the active ingredient within the base layers 1, 2 for maturation (see Roreger at column 3, lines 28-45; and Fig. 1). Further, Roreger discloses that each base layer 1, 2 includes protective layers 3, 4 which may be detachable (see Roreger at column 4, lines 39-41).

Initially, it is noted that independent claims 69 recites a pair of press rolls arranged to draw two resin films, with each of the resin films being provided with an orally administrable edible agent layer having a predetermined thickness on a surface thereof, and a winding shaft arranged to draw and delaminate only one of the two resin films. In this regard, it is noted that Roreger discloses that the active substance is applied to a surface of at least one of the base layers 1 and 2 (see Roreger at column 3, lines 36-37). As indicated above, it is asserted that the base layers 1 and 2 of Roreger correspond to the resin films of the claimed invention (*i.e.*, the films on which the edible agent layers are formed). However, during the telephone interview of

October 8, 2009, the Examiner clarified that the layers 1 and 2 are being interpreted as also including the active ingredient, and are thus being interpreted as the “edible agent layers,” and that the protective layers 3, 4 are being interpreted as the “resin films” of independent claim 69.

In this regard, it is first noted that Roreger clearly discloses that reference numbers 1 and 2 correspond to layers of the matrix base material, that the active substance is applied to at least one of the layers 1, 2, and that both base material layers 1, 2 (and not the active ingredients) are joined together such that the active substance medium does not emerge at the edges of the weblike matrix 14 and such that the interfaces of the base material layers 1, 2 are bonded inseparably, as shown in Fig. 2 (see Roreger at column 3, lines 36-37; column 4, lines 38-39; column 5, line 66 through column 6, line 5; and Fig. 2). Thus, as Roreger clearly discloses that the reference numbers 1 and 2 correspond to the base material layers, and that the active substance is formed on the layers 1 and 2 as shown in Fig. 2, it is respectfully submitted that the layers 1 and 2 do not constitute the edible agent layers of claim 69.

Rather, it is respectfully submitted that the layers 1 and 2 correspond to the resin films of the claimed invention (*i.e.*, the films on which the edible agent layers are formed). In this regard, Roreger does not disclose or suggest a winding shaft arranged to draw and delaminate only one of the two resin films sandwiching the orally administrable edible agent layers, as required by independent claim 69, because Roreger discloses that the base layers 1 and 2 are irreversibly bonded, and that it is necessary that the interfaces of the base layers 1 and 2 are bonded inseparably (see Roreger at column 5, line 66 through column 6, line 5).

Further, even if the interpretation of the base material layers 1 and 2 as the edible agent layers is proper and the interpretation of the protective layers 3 and 4 as the resin layers of independent claim 69 is proper, Roreger does not disclose *a winding shaft arranged to draw and delaminate only one of the two resin films sandwiching the orally administrable edible agent layers* conveyed from the pair of press rolls to the delamination roll in a direction different from the conveying direction from the pair of press rolls to the delamination roll, as required by independent claim 69.

Rather, Roreger discloses that protective layers 3 and 4 are removed from the base layers 1 and 2 by the winders 5, 6 prior to application of the active substance (see Roreger at column 4, lines 46-49). Thus, Roreger does not disclose a winding shaft arranged to draw and delaminate only one of the two resin films sandwiching the orally administrable edible agent layers, as

required by independent claim 69, because Roreger discloses that the winders 5, 6 remove the protective layers 3 and 4 prior to the application of the active substance. Thus, as the winders 5, 6 remove the protective layers 3 and 4 prior to the application of the active substance, the protective layers 3 and 4 never sandwich the active substance, and therefore the winders 5, 6 of Roreger are not arranged to draw and delaminate only one of the two resin films sandwiching the orally administrable edible agent layers, as required by independent claim 69.

Further, as noted by the Examiner on page 6 of the Office Action of July 16, 2009, Roreger does not disclose an orally administrable edible agent of laminate film form (see Office Action of July 16, 2009 at page 6, lines 9-11). In this regard, the Examiner cites Nogami as disclosing a layered edible film for administering an active agent in which the layers are sprayed onto a film and dried, and concludes that it would have been obvious to one of ordinary skill in the art to make the layered edible film of Nogami by the method of Roreger so as to arrive at the claimed invention (see Office Action of July 16, 2009 at page 6, lines 12-15; and page 7, line 20 through page 8, line 1).

Nogami discloses an orally administered agent which includes a combination of drug-containing layers 11, water-swelling gel-forming layers 12, and intermediate layers 13 (see Nogami at paragraph [0082], lines 1-5; and Fig. 5). However, Nogami does not disclose a pressure bonding apparatus for producing an orally administrable edible agent, and therefore also does not disclose a pressure bonding apparatus for producing an orally administrable edible agent which includes *a winding shaft arranged to draw and delaminate only one of the two resin films sandwiching the orally administrable edible agent layers in a direction different from the conveying direction, and a conveyance mechanism arranged to convey the other of the two resin films, which retains the orally administrable edible agent layers, in the conveying direction*, as required by independent claim 69.

Accordingly, as none of the Roreger and Nogami references discloses or suggests a pressure bonding apparatus which includes a winding shaft arranged to draw and delaminate only one of the two resin films sandwiching the orally administrable edible agent layers in a direction different from the conveying direction, and a conveyance mechanism arranged to convey the other of the two resin films, which retains the orally administrable edible agent layers, in the conveying direction, as required by independent claim 69, the combination of the Roreger and Nogami references also does not disclose or suggest a pressure bonding apparatus

which includes a winding shaft arranged to draw and delaminate only one of the two resin films sandwiching the orally administrable edible agent layers in a direction different from the conveying direction, and a conveyance mechanism arranged to convey the other of the two resin films, which retains the orally administrable edible agent layers, in the conveying direction, as required by independent claim 69. Accordingly, it is respectfully submitted that one of ordinary skill in the art would not have modified Roreger in view of Nogami so as to result in or render obvious the invention of independent claim 69.

Therefore, in view of the above, it is respectfully submitted that independent claim 69 is clearly allowable over the prior art of record. Further, it is respectfully submitted that claims 70-76 are also allowable over the prior art, at least by virtue of their dependency from claim 69.

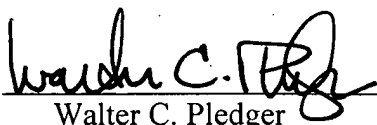
II. Conclusion

In view of the foregoing, Appellants respectfully request that the Examiner's decision to finally reject claims 39-76 be reversed.

This brief is submitted with the requisite fee of \$270.00. **The Commissioner is authorized to charge any deficiency or to credit any overpayment of fees associated with this communication to Deposit Account No. 23-0975.**

Respectfully submitted,

Yasuo HAYASHI et al.

By 
Walter C. Pledger
Registration No. 55,540
Attorney for Appellants

WCP/lkd
Washington, D.C. 20005-1503
Telephone (202) 721-8200
Facsimile (202) 721-8250
January 19, 2010

CLAIMS APPENDIX – claims on appeal

39. A method for producing an orally administrable edible agent of laminate film form, the method comprising:

forming a plurality of orally administrable edible agent layers, wherein each orally administrable edible agent layer has a predetermined thickness and is formed on a surface of a respective resin film by coating and drying;

joining together two orally administrable edible agent layers so that orally administrable edible agent layer surfaces face each other and the orally administrable edible agent layers are sandwiched between the resin films of the two orally administrable edible agent layers, and pressurizing the resin films at back surfaces by a pair of press rolls so as to bond the orally administrable edible agent layers together such that ingredients of each of the orally administrable edible agent layers do not permeate the other of the orally administrable edible agent layers, wherein the orally administrable edible agent layers include the same ingredients or different ingredients; and

delaminating only one of the two resin films by conveying the two resin films sandwiching the bonded orally administrable edible agent layers in a substantially tangential direction at a pressurization zone of the pair of press rolls, and drawing only one of the two resin films sandwiching the bonded orally administrable edible agent layers in a direction different from the conveying direction along a peripheral surface of a delamination roll disposed in the conveying direction while continuously conveying the other resin film retaining the bonded orally administrable edible agent layers in the conveying direction.

40. The method for producing an orally administrable edible agent of laminate film form according to claim 39, wherein the one resin film to be delaminated in said delaminating of only

one of the two resin films is previously subjected to release treatment at least on a surface provided with the orally administrable edible agent layer.

41. The method for producing an orally administrable edible agent of laminate film form according to claim 39, wherein said pressurizing of the resin films at back surfaces by the pair of press rolls comprises pressurizing the resin films at a pressure of 0.05 to 1.5 MPa.

42. The method for producing an orally administrable edible agent of laminate film form according to claim 39, wherein a temperature of the orally administrable edible agent layers is 50°C to 180°C during said joining together of the two orally administrable edible agent layers.

43. The method for producing an orally administrable edible agent of laminate film form according to claim 42, further comprising:

cooling the bonded orally administrable edible agent layers to a temperature at least 10°C lower than the temperature of the orally administrable edible agent layers during said joining together of the two orally administrable edible agent layers, and such that the temperature of the cooled orally administrable edible agent layers is higher than 0°C, wherein said cooling of the bonded orally administrable edible agent layers occurs after said joining together of the two orally administrable edible agent layers and before said delaminating of only one of the two resin films.

44. The method for producing an orally administrable edible agent of laminate film form according to claim 42, wherein each of the bonded orally administrable edible agent layers includes an edible thermoplastic substance.

45. The method for producing an orally administrable edible agent of laminate film form according to claim 44, wherein the edible thermoplastic substance includes at least one selected from the group consisting of amylose, carboxymethyl cellulose potassium, carboxymethyl cellulose sodium, carboxymethyl cellulose calcium, alkyl ester alginate, sodium alginate, ethylcellulose, eudragit, carboxymethylethylcellulose, carboxymethyl starch, carboxymethyl cellulose, agar, gelatin, shellac, dextran, dextrin, starch, tragacanth, hydroxyethylcellulose, hydroxypropylcellulose, hydroxypropylmethylcellulose, hydroxypropylmethylcellulose phthalate, polyvinylpyrrolidone, methacrylic acid copolymer, and methylcellulose phthalate.

46. The method for producing an orally administrable edible agent of laminate film form according to claim 39, wherein a thickness of each of the bonded orally administrable edible agent layers is 1 to 300 μm .

47. The method for producing an orally administrable edible agent of laminate film form according to claim 39, wherein the bonded orally administrable edible agent layers are self-supporting laminated films.

48. The method for producing an orally administrable edible agent of laminate film form according to claim 47, further comprising:

delaminating the other resin film retaining the orally administrable edible agent layers so as to finally delaminate the resin films from the bonded orally administrable edible agent layers.

49. A method for producing an orally administrable edible agent of laminate film form, comprising:

forming a plurality of orally administrable edible agent layers, wherein each orally administrable edible agent layer has a predetermined thickness and is formed on a surface of a respective resin film by coating and drying;

joining together first and second orally administrable edible agent layers so that orally administrable edible agent layer surfaces face each other and the orally administrable edible agent layers are sandwiched between corresponding first and second resin films of the first and second orally administrable edible agent layers, and pressurizing the resin films at back surfaces by a pair of press rolls so as to bond the orally administrable edible agent layers together such that ingredients of each of the first and second orally administrable edible agent layers do not permeate the other of the first and second orally administrable edible agent layers, wherein the orally administrable edible agent layers include the same ingredients or different ingredients;

delaminating only one of the first and second resin films by conveying the first and second resin films sandwiching the bonded orally administrable edible agent layers in a substantially tangential direction at a pressurization zone of the pair of press rolls, and drawing only one of the first and second resin films sandwiching the bonded orally administrable edible agent layers in a direction different from the conveying direction along a peripheral surface of a delamination roll disposed in the conveying direction while continuously conveying the other of

the first and second resin films retaining the bonded orally administrable edible agent layers in the conveying direction;

joining together a third orally administrable edible agent layer and the bonded first and second orally administrable edible agent layers so that orally administrable edible agent layer surfaces face each other and the first, second and third orally administrable edible agent layers are sandwiched between a corresponding third resin film of the third orally administrable edible agent layer and the other of the first and second resin films retaining the bonded first and second orally administrable edible agent layers, and pressurizing the resin films at back surfaces by the pair of press rolls so as to bond the first, second and third orally administrable edible agent layers together such that ingredients of each of the orally administrable edible agent layers do not permeate any other of the orally administrable edible agent layers, wherein the third orally administrable edible agent layer includes the same ingredients or different ingredients as that of the bonded first and second orally administrable edible agent layers; and

delaminating only one of the resin films sandwiching the bonded first, second and third orally administrable edible agent layers by conveying the resin films sandwiching the bonded first, second and third orally administrable edible agent layers in the substantially tangential direction at the pressurization zone of the pair of press rolls, and drawing only one of the resin films sandwiching the bonded first, second and third orally administrable edible agent layers in a direction different from the conveying direction along the peripheral surface of the delamination roll disposed in the conveying direction while continuously conveying the other of the resin films retaining the first, second and third orally administrable edible agent layers in the conveying direction.

50. The method for producing an orally administrable edible agent of laminate film form according to claim 49, wherein the one resin film to be delaminated in said delaminating of only one of the first and second resin films is previously subjected to release treatment at least on a surface provided with the orally administrable edible agent layer.

51. The method for producing an orally administrable edible agent of laminate film form according to claim 49, wherein the one resin film to be delaminated in said delaminating of only one of the resin films sandwiching the bonded first, second and third orally administrable edible agent layers is previously subjected to release treatment at least on a surface provided with the orally administrable edible agent layer.

52. The method for producing an orally administrable edible agent of laminate film form according to claim 49, wherein said pressurizing of the resin films in said joining together of the first and second orally administrable edible agent layers and in said joining together of the third orally administrable edible agent layer and the bonded first and second orally administrable edible agent layers comprises pressurizing the resin films at a pressure of 0.05 to 1.5 MPa.

53. The method for producing an orally administrable edible agent of laminate film form according to claim 49, wherein a temperature of the orally administrable edible agent layers is 50°C to 180°C during said joining together of the first and second orally administrable edible agent layers and during said joining together of the third orally administrable edible agent layer and the bonded first and second orally administrable edible agent layers.

54. The method for producing an orally administrable edible agent of laminate film form according to claim 49, wherein a thickness of each of the bonded first, second and third orally administrable edible agent layers is 1 to 300 μm .

55. The method for producing an orally administrable edible agent of laminate film form according to claim 49, wherein the bonded first, second and third orally administrable edible agent layers are self-supporting laminated films.

56. A method for producing an orally administrable edible agent of laminate film form, comprising:

forming a plurality of orally administrable edible agent layers, wherein each orally administrable edible agent layer has a predetermined thickness and is formed on a surface of a respective resin film by coating and drying;

winding each of the orally administrable edible agent layers into a roll so as to form a plurality of rolled films;

unwinding and joining together two rolled films so that surfaces of the orally administrable edible agent layers of the two rolled films face each other and the orally administrable edible agent layers are sandwiched between the resin films of the two rolled films, and pressurizing the resin films at back surfaces by a pair of press rolls so as to bond the orally administrable edible agent layers together such that ingredients of each of the orally administrable edible agent layers do not permeate the other of the orally administrable edible agent layers, wherein the orally administrable edible agent layers include the same ingredients or different ingredients; and

delaminating only one of the two resin films by conveying the two resin films sandwiching the bonded orally administrable edible agent layers in a substantially tangential direction at a pressurization zone of the pair of press rolls, and drawing only one of the two resin films sandwiching the bonded orally administrable edible agent layers in a direction different from the conveying direction along a peripheral surface of a delamination roll disposed in the conveying direction while continuously conveying the other resin film retaining the bonded orally administrable edible agent layers in the conveying direction.

57. The method for producing an orally administrable edible agent of laminate film form according to claim 56, wherein the one resin film to be delaminated in said delaminating of only one of the two resin films is previously subjected to release treatment on both a front surface to provided with the orally administrable edible agent layer and an opposite back surface, and the other resin film on which the bonded orally administrable edible agent layers are to be retained in said delaminating of only one of the two resin films is previously subjected to release treatment at least on a back surface which is not to be provided with an orally administrable edible agent layer.

58. The method for producing an orally administrable edible agent of laminate film form according to claim 56, wherein said pressurizing of the resin films at back surfaces by the pair of press rolls comprises pressurizing the resin films at a pressure of 0.05 to 1.5 MPa.

59. The method for producing an orally administrable edible agent of laminate film form according to claim 56, wherein a temperature of the orally administrable edible agent layers is 50°C to 180°C during said joining together of the two rolled films.

60. The method for producing an orally administrable edible agent of laminate film form according to claim 56, wherein a thickness of each of the bonded orally administrable edible agent layers is 1 to 300 μm .

61. The method for producing an orally administrable edible agent of laminate film form according to claim 56, wherein the bonded orally administrable edible agent layers are self-supporting laminated films.

62. A method for producing an orally administrable edible agent of laminate film form, comprising:

forming a plurality of orally administrable edible agent layers, wherein each orally administrable edible agent layer has a predetermined thickness and is formed on a surface of a respective resin film by coating and drying;

winding each of the orally administrable edible agent layers into a roll so as to form a plurality of rolled films;

unwinding and joining together first and second rolled films so that surfaces of corresponding first and second orally administrable edible agent layers of the first and second rolled films face each other and the orally administrable edible agent layers are sandwiched between corresponding first and second resin films of the first and second rolled films, and

pressurizing the resin films at back surfaces by a pair of press rolls so as to bond the orally administrable edible agent layers together such that ingredients of each of the first and second orally administrable edible agent layers do not permeate the other of the first and second orally administrable edible agent layers, wherein the orally administrable edible agent layers include the same ingredients or different ingredients;

delaminating only one of the first and second resin films by conveying the first and second resin films sandwiching the bonded orally administrable edible agent layers in a substantially tangential direction at a pressurization zone of the pair of press rolls, and drawing only one of the first and second resin films sandwiching the bonded orally administrable edible agent layers in a direction different from the conveying direction along a peripheral surface of a delamination roll disposed in the conveying direction while continuously conveying the other of the first and second resin films retaining the bonded first and second orally administrable edible agent layers in the conveying direction;

winding the resin film retaining the bonded orally administrable edible agent layers into a roll;

unwinding and joining together a third rolled film and the roll having the bonded first and second orally administrable edible agent layers so that surfaces of a corresponding third orally administrable edible agent layer of the third rolled film and one of the first and second orally administrable edible agent layers face each other and the first, second and third orally administrable edible agent layers are sandwiched between a corresponding third resin film of the third rolled film and the other of the first and second resin films retaining the bonded first and second orally administrable edible agent layers, and pressurizing the resin films at back surfaces by the pair of press rolls so as to bond the first, second and third orally administrable edible

agent layers together such that ingredients of each of the orally administrable edible agent layers do not permeate any other of the orally administrable edible agent layers, wherein the third orally administrable edible agent layer includes the same ingredients or different ingredients as that of the bonded first and second orally administrable edible agent layers; and

delaminating only one of the resin films sandwiching the bonded first, second and third orally administrable edible agent layers by conveying the resin films sandwiching the bonded first, second and third orally administrable edible agent layers in the substantially tangential direction at the pressurization zone of the pair of press rolls, and drawing only one of the resin films sandwiching the bonded first, second and third orally administrable edible agent layers in a direction different from the conveying direction along the peripheral surface of the delamination roll disposed in the conveying direction while continuously conveying the other of the resin films retaining the bonded first, second and third orally administrable edible agent layers in the conveying direction.

63. The method for producing an orally administrable edible agent of laminate film form according to claim 62, wherein the one resin film to be delaminated in said delaminating of only one of the resin films sandwiching the bonded first, second and third orally administrable edible agent layers is previously subjected to release treatment on both a front surface to be provided with an orally administrable edible agent layer and an opposite back surface, and the other of the resin films on which the bonded first, second and third orally administrable edible agent layers are to be retained in said delaminating of only one of the resin films sandwiching the bonded first, second and third orally administrable edible agent layers is previously subjected to release

treatment at least on a back surface which is not to be provided with an orally administrable edible agent layer.

64. The method for producing an orally administrable edible agent of laminate film form according to claim 62, wherein the one resin film to be delaminated in said delaminating of only one of the first and second resin films is previously subjected to release treatment on both a front surface to be provided with an orally administrable edible agent layer and an opposite back surface, and the other of the resin films on which the bonded first and second orally administrable edible agent layers are to be retained in said delaminating of only one of the first and second resin films is previously subjected to release treatment at least on a back surface which is not to be provided with an orally administrable edible agent layer.

65. The method for producing an orally administrable edible agent of laminate film form according to claim 62, wherein said pressurizing of the resin films in said joining together of the first and second rolled films and in said joining together of the third rolled film and the roll having the bonded first and second orally administrable edible agent layers comprises pressurizing the resin films at a pressure of 0.05 to 1.5 MPa.

66. The method for producing an orally administrable edible agent of laminate film form according to claim 62, wherein a temperature of the orally administrable edible agent layers is 50°C to 180°C during said joining together of the first and second rolled films and during said joining together of the third rolled film and the roll having the bonded first and second orally administrable edible agent layers.

67. The method for producing an orally administrable edible agent of laminate film form according to claim 62, wherein a thickness of each of the bonded first, second and third orally administrable edible agent layers is 1 to 300 μm .

68. The method for producing an orally administrable edible agent of laminate film form according to claim 62, wherein the bonded first, second and third orally administrable edible agent layers are self-supporting laminated films.

69. A pressure bonding apparatus for producing an orally administrable edible agent of laminate film form, comprising:

a pair of press rolls arranged to draw two resin films, each of said resin films being provided with an orally administrable edible agent layer having a predetermined thickness on a surface thereof, such that orally administrable edible agent layer surfaces face each other and said orally administrable edible agent layers are sandwiched between said resin films, said pair of press rolls being further arranged to pressurize said resin films at back surfaces thereof so as to bond said orally administrable edible agent layers together such that ingredients of each of said orally administrable edible agent layers do not permeate the other of said orally administrable edible agent layers;

a delamination roll having a diameter of 6 cm or less disposed at a position forward of said pair of press rolls in a conveying direction of said pair of press rolls and in a substantially tangential direction at a pressurization zone of said pair of press rolls;

a winding shaft arranged to draw and delaminate only one of said two resin films sandwiching said orally administrable edible agent layers conveyed from said pair of press rolls to said delamination roll in a direction different from the conveying direction from said pair of press rolls to said delamination roll, along a peripheral surface of said delamination roll; and

a conveyance mechanism arranged to convey the other of said two resin films, which retains said orally administrable edible agent layers, in the conveying direction from said pair of press rolls to said delamination roll.

70. The pressure bonding apparatus for producing an orally administrable edible agent of laminate film form according to claim 69, wherein said delamination roll is rotatably disposed so as to rotate with movement of said one resin film.

71. The pressure bonding apparatus for producing an orally administrable edible agent of laminate film form according to claim 69, wherein said winding shaft is disposed in a position so as to draw said one resin film at an angle of 45° or more relative to the conveying direction of said other of said two resin films with said delamination roll as a starting point.

72. The pressure bonding apparatus for producing an orally administrable edible agent of laminate film form according to claim 69, further comprising:

a pair of unwinding rolls arranged to respectively feed said two resin films to said pair of press rolls; and

a winding roll arranged to wind up said other of said two resin films, which retains said orally administrable edible agent layers,

wherein said unwinding roll and said winding roll have substantially the same dimension and structure and are interchangeable.

73. The pressure bonding apparatus for producing an orally administrable edible agent of laminate film form according to claim 69, further comprising:

a slitter arranged to cut said other of said two resin films, which retains said orally administrable edible agent layers, into narrow strips in parallel with the conveying direction; and

a plurality of winding reels arranged to wind up the narrow strips, respectively, each of said winding reels including a winding shaft portion and a flange portion,

wherein said plurality of winding reels are arranged so that said winding shaft portions are staggered in backward and forward directions without gaps, and so that said flange portions are aligned in the backward and forward directions.

74. The pressure bonding apparatus for producing an orally administrable edible agent of laminate film form according to claim 73, further comprising:

a shaft arranged to support said plurality of winding reels; and

frames arranged so as to support both ends of said shaft, respectively, wherein one end of said shaft can be supported so as to be cantilevered by one of said frames, and the other of said frames can be brought down and stood up.

75. The pressure bonding apparatus for producing an orally administrable edible agent of laminate film form according to claim 73, further comprising:

a shaft arranged to rotatably support each of said winding reels; and

a spring disposed at one end of said shaft and biased toward an opposite end of said shaft, said spring being arranged such that side walls of each winding reel are pressed by said spring, and such that a biasing force of said spring causes rotation of the shaft to be transmitted to said winding reels.

76. The pressure bonding apparatus for producing an orally administrable edible agent of laminate film form according to claim 69, further comprising:

a slit arranged to cut said other of said two resin films, which retains said orally administrable edible agent layers, into narrow strips in parallel with the conveying direction, said slit being switchable between an ON state in which said slit cuts said other of said two resin films into narrow strips in parallel with the conveying direction, and an OFF state in which said other resin film passes through said slit without being cut;

a shaft arranged to support a plurality of winding reels, said winding reels being arranged to wind up said narrow strips, respectively, from said slit in the ON state; and

a winding roll arranged to wind up said other resin film conveyed by said conveyance mechanism through said slit in the OFF state,

wherein said winding roll and said shaft that supports said plurality of winding reels are interchangeable.

EVIDENCE APPENDIX

None.

RELATED PROCEEDINGS APPENDIX

None.